

PTO/SB/21 (09-04)

Approved for use through 07/31/2006. OMB 0651-0031

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**TRANSMITTAL  
FORM**

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

8

Application Number

10/712,546

Filing Date

November 12, 2003

First Named Inventor

Joseph S. Podolski

Art Unit

1614

Examiner Name

Attorney Docket Number

07189.0028.CPUS02

**ENCLOSURES (Check all that apply)**

<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
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<input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53		
<b>Remarks</b>		

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm Name	Howrey Simon Arnold & White, LLP		
Signature			
Printed name	Teddy C. Scott, Jr., Ph.D.		
Date	October 15, 2004	Reg. No.	53,573

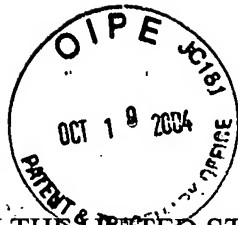
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Signature			
Typed or printed name	Teddy C. Scott, Jr., Ph.D.	Date	October 15, 2004

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**PATENT**

Attorney Docket No. 07189.0028.CPSU02

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s): Joseph S. Podolski  
App. No.: 10/712,546  
Filing Date: November 12, 2003  
Title: METHODS AND COMPOSITIONS  
WITH TRANS-CLOMIPHENE FOR  
TREATING WASTING AND  
LIPODYSTROPHY  
Art Unit: 1614

**CERTIFICATE OF MAILING**

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this date:

10/15/04  
Date

*Teddy C. Scott*  
Teddy C. Scott  
Registration No. 53,573

**INFORMATION DISCLOSURE STATEMENT  
PURSUANT TO 37 C.F.R. §§ 1.56, 1.97 and 1.98**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In compliance with 37 C.F.R. § 1.97 and the continuing duty of disclosure under 37 C.F.R. § 1.56, Applicants call to the attention of the Examiner the references listed on the attached Forms PTO/SB/08A and PTO/SB/08B. It is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Forms PTO/SB/08A and PTO/SB/08B be considered by the Examiner and made of record.

In accordance with 37 C.F.R. § 1.97(g), this Information Disclosure Statement is not to be construed as a representation that a search has been made. In accordance with 37 C.F.R. § 1.97(h), this Information Disclosure Statement is not to be construed as an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

This application is a continuation-in-part of International Application No PCT/US02/21524, filed July 9, 2002, the national stage of which is Application No. 10/483,458 (the "Priority Application"), and is relied upon for an earlier effective filing date under 35 U.S.C. § 120. The documents cited on Forms PTO/SB/08A and PTO/SB/08B were cited and submitted to the Patent and Trademark Office in the Priority Application. In accordance with 37 C.F.R. § 1.98(d), copies of the documents are not provided herewith.

This Information Disclosure Statement is being filed prior to the receipt of a first Office Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b)(3).

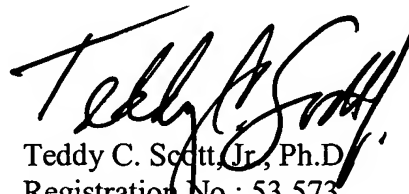
No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to this document, the Commissioner is hereby authorized to deduct the fees from Howrey Simon Arnold & White, LLP Deposit Account 08-3038. referencing docket number 07189.0028.CPUS02.

Respectfully submitted,

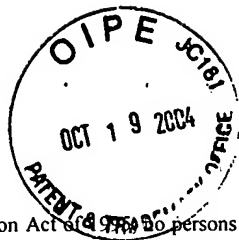
HOWREY SIMON ARNOLD & WHITE, LLP

Dated: October 15, 2004

By:

  
Teddy C. Scott, Jr., Ph.D.  
Registration No.: 53,573  
Customer No.: 22930

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PTO/SB/08A (10-01)

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Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>	
				<b>Application Number</b>	10/712,546
				<b>Filing Date</b>	November 12, 2003
				<b>First Named Inventor</b>	Joseph S. Podolski
				<b>Group Art Unit</b>	1614
				<b>Examiner Name</b>	
Sheet	1	of	5	<b>Attorney Docket Number</b>	07189.0028.CPUS02

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
	A1	4,061,733	12/06/1977	Gunjekar	
	A2	5,728,688	03/1998	Labrie	
	A3	5,861,389	01/1999	Radlmaier	
	A4	6,096,338	08/01/2000	Lacy	
	A5	6,126,969	10/03/2000	Shah	
	A6	6,129,933	10/10/2000	Oshlack	
	A7	6,143,353	11/07/2000	Oshlack	
	A8	6,190,591	02/20/2001	Van Lengerich	
	A9	6,221,399	04/24/2001	Rolfes	
	A10	6,248,363 B1	06/19/200-1	Patel	
	A11	6,391,920 B1	05/21/2002	Fisch	
	A12	US 2002/0120012 A1	09/29/2002	Fisch	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
	B1	EP 0888775 A2	07/01/1999	Medical College of Hampton Roads		
	B2	WO 03/005954 A2	01/23/2003	Zonagen, Inc.		
	B3	WO 95/35093	12/28/1995	University of Nebraska Board of Regents		
	B4	JP 4-312522				
	B5	WO 01/91744 A1	12/20/2001	Fisch		

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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds codes of USPTO Patent Documents as [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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			<b>Application Number</b>	10/712,546	
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			<b>First Named Inventor</b>	Joseph S. Podolski	
			<b>Group Art Unit</b>	1614	
<b>Examiner Name</b>					
<b>Sheet</b>	2		5	<b>Attorney Docket Number</b>	07189.0028.CPUS02

<b>OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS</b>			
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	C1	Ben-Jonathan, N., et al., "Dopamine as a Prolactin (PRL) Inhibitor," Endocr. Rev. 22(6), pp.724-63 (2001)	
	C2	Breznik, R., et al., "Effectiveness of Antiestrogens in Infertile Men," Arch. Androl., Vol. 31(1), pp. 43-48 (1993)	
	C3	Check, J., et al., "Empirical Therapy of the Male with Clomiphene in Couples with Unexplained Infertility" Int. Journal Fertil., Vol. 34(2), pp. 120-122 (1989)	
	C4	Cooper, A., et al., "The Effects of Clomiphene in Impotence A Clinical and Endocrine Study," British Journal of Psychiatry, Vol. 120, pp. 327-330 (1972)	
	C5	Cunningham, G., et al., "Testosterone Replacement Therapy and Sleep-Related Erections in Hypogonadal Men," J. Clin. Endocrinol. Metab., Vol. 70, No. 3, pp. 792-797 (1990)	
	C6	Dangprasit, P., et al., "Development of Diclofenac Sodium Controlled Release Solid Dispersions by Spray Drying Using Optimization Strategy I. Powder Formulation," Drug. Devel. And Industrial Pharm. 21(20), pp.2323-2337 (1995)	
	C7	Davidson, J., et al., "Effects of Androgen on Sexual Behavior in Hypogonadal Men," J. Clin. Endocrinol. Metab., Vol. 48, No. 6, pp. 955-958 (1979)	
	C8	Ernst, S., et al., "Stereochemistry of Geometric Isomers of Clomiphene: A Correction of the Literature and A Reexamination of Structure-Activity Relationships," J. Pharmaceut. Sci., Vol. 65, pp. 148-150 (1976)	

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				<b>Group Art Unit</b>	1614
				<b>Examiner Name</b>	
Sheet	3		5	<b>Attorney Docket Number</b>	07189.0028.CPUS02

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher city and/or country where published	T <sup>2</sup>
	C9	Feldman, H., et al., "Age Trends in the Level of Serum Testosterone and Other Hormones in Middle-Aged Men: Longitudinal Results from the Massachusetts Male Aging Study," J Clin Endocrinol Metab. 87(2), pp.589-598 (2002)	
	C10	Fuse, H., et al., "Changes in Seminal Plasma Transferring Concentration Following Administration of Clomiphene Citrate," Archives of Andrology, Vol. 31, pp. 139-145 (1993)	
	C11	Guay, A., et al., "Effect of Raising Endogenous Testosterone Levels in Impotent Men with Secondary Hypogonadism: Double Blind Placebo-Controlled Trial with Clomiphene Citrate," Journal of Clinical Endocrinology and Metabolism, Vol. 80, No. 12, pp. 3546-3552 (1995)	
	C12	Guay, A., et al., "Possible Hypothalamic Impotence," Urology, Vol. 38, No. 4, pp. 317-322 (1991)	
	C13	Guay A., et al., "Results of Double Blinded Treatment With Clomiphene Citrate In Patients With Hypogonadotropic Hypogonadism," Annual Meeting of the Endocrine Society, Abstract No. 386, (June 1993)	
	C14	Hirshkowitz, M., et al., "Androgen and Sleep-Related Erections," J. Psychosomatic Research, Vol. 42, No. 6, pp. 541-546 (1997)	
	C15	Homonnai, Z., et al., "Clomiphene Citrate Treatment in Oligozoospermia: Comparison Between Two Regimens of Low-Dose Treatment," Fertility And Sterility, Vol. 60, No. 5, pp. 801-804 (1988)	
	C16	Jarow, J., "Nonsurgical Treatment of Male Infertility: Empiric Therapy," Therapy, Chapter 23, pp. 410-422 (date of Publication Not Available)	

<b>Examiner Signature</b>		<b>Date Considered</b>	
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				<b>Group Art Unit</b>	1614	
<b>Examiner Name</b>						
<b>Sheet</b>	4		5	<b>Attorney Docket Number</b>	07189.0028.CPUS02	

<b>OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS</b>			
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	C17	Kharenko, A., et al., "Controlled Release From Oral Formulations Based on Interpolymeric Polymethacrylic Acid – Polyethylene Glycol Complex," Proceed. Intern. Symp. Control Rel. Bioact. Mater., Vol. 22, pp. 232-233 (1995)	
	C18	Matsumoto, A., et al., "Human Chorionic Gonadotropin and Testicular Function: Stimulation of Testosterone, Testosterone Precursors, and Sperm Production Despite High Estradiol Levels," Journal of Clinical Endocrinol. And Metab. Vol. 56, No. 4, pp. 720-728 (1983)	
	C19	Merck Index, 13th Ed., Entry 2410, p. 417 (2001)	
	C20	Meshali, M., et al., "Effect of Interpolymer Complex Formation of Chitosan With Pectin or Acacia on the Release Behaviour of Chlorpromazine HCl" Int. J. Phar., Vol. 89, pp. 177-181 (1993)	
	C21	Morales, A., et al., "Andropause: A Misnomer For A True Clinical Entity," J. Urol., Vol. 163, No. 3, pp. 705-12 (March 2000) Abstract	
	C22	Purvis, K., et al., "Stability of Sperm Characteristics in Men with Disturbances in Sperm Quality," Int. Journal Androl., 12, pp. 171-178 (1989)	
	C23	Soderguard, R., et al., "Calculation of Free and Bound Fractions of Testosterone and Estradiol-17 $\beta$ to Human Plasma Proteins at Body Temperature," J. Steroid Biochem, Vol. 16, pp. 801-810 (1982)	
	C24	Sternbach, et al., "Age-associated Testosterone Decline in Men: Clinical Issues for Psychiatry," Am. J. Psychiatry, Vol. 155, No. 10, pp. 1310-8 (1998) Abstract	

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				<b>Group Art Unit</b>	1614	
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<b>Attorney Docket Number</b>	07189.0028.CPUS02					
Sheet	5		5			

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
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	C25	Suzuki, et al., "Endocrine Environment of Benign Prostatic Hyperplasia: Prostate Size and Volume are Correlated with Serum Estrogen Concentration," Scand. J. Urol. Nephrol., Vol. 29, No. 1, pp. 65-8 (1995) Abstract	
	C26	Tenover, J., et al., "Serum Bioactive and Immunoreactive Follicle-Stimulating Hormone Levels and the Response to Clomiphene in Healthy Young and Elderly Men," Journal Clinical Endocrinol. And Metab., Vol. 64, No. 6, pp. 1103-1108 (1987)	
	C27	Tenover, J., et al., "The Effects of Aging in Normal Men on Bioavailable Testosterone and Luteinizing Hormone Secretion: Response to Clomiphene Citrate," Journal Clinical Endocrinol. Metab., Vol. 65, No. 6, pp. 1118-1126 (1987)	
	C28	U.S. Pharmacopeia, United States Pharmacopeia, 26 <sup>th</sup> Ed., pp. 484-485 (2003)	

<b>Examiner Signature</b>		<b>Date Considered</b>	
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